



MONDAY 1/09
State of Wisconsin
2005 - 2006 LEGISLATURE

D-NOTE

LRBs0425/P1

DAK:lmk:ch

↑
keep

~~PRELIMINARY DRAFT - NOT READY FOR INTRODUCTION~~

ASSEMBLY SUBSTITUTE AMENDMENT,

TO 2005 ASSEMBLY BILL 830

✓

REGENERATE

1 AN ACT *to repeal* 157.06 (11) and 157.06 (12); *to amend* 157.06 (2) (j), 157.06 (4)
2 (title), 157.06 (4) (am) (intro.), 157.06 (4) (b) and 157.06 (5) (bm); *to repeal and*
3 *recreate* 157.06 (title); and *to create* 157.06 (4m), 157.06 (4r), 157.06 (9m) and
4 979.01 (5) of the statutes; **relating to:** anatomical gifts and the powers and
5 duties of coroners and medical examiners, granting rule-making authority, and
6 providing an exemption from emergency rule procedures. ✓

Analysis by the Legislative Reference Bureau

Currently, an individual who is at least 18 years of age may make an anatomical gift (donation of all or part of his or her body to take effect at the time or after he or she irreversibly ceases circulatory and respiratory functions or all functions of the brain). Also, certain members of a decedent's family or his or her health care agent under a power of attorney for health care may, under an order of priority, make an anatomical gift of all or a part of the decedent's body. If a decedent is within the custody of a coroner or medical examiner and there is no evidence that the decedent made or refused to make an anatomical gift, under certain circumstances the coroner or medical examiner may release and permit the removal of a part from the decedent's body for use in transplantation or therapy.

This substitute amendment creates requirements related to removal of a body part from a decedent who is within the jurisdiction of a coroner or medical examiner ^{and who} has made an anatomical gift or whose family or health care agent has made an anatomical gift of all or part of the decedent's body. ^{For such a person,} a physician may remove a vascularized organ (a heart, lung, liver, pancreas, kidney, intestine, or other organ that requires the continuous circulation of blood to remain useful for purposes of transplantation) within a time period in which the organ may be preserved for purposes of transplantation if (1) immediately after the hospital in which the decedent is located contacts the organ procurement organization concerning the potential donation, the organ procurement organization provides notice, by oral conversation, of the ~~intended removal~~ ^{referral} to the coroner or medical examiner or his or her designee and provides notice of the ~~intended removal~~ ^{referral} to the district attorney or his or her designee; and (2) the coroner or medical examiner or his or her designee has the opportunity to be present during the vascularized organ's removal if in ~~his or her~~ ^{his or her} judgment the organ may be necessary in determining the cause of death. However, if, in the judgment of the coroner, medical examiner, or designee, the organ may be necessary in determining the cause of death, the coroner, medical examiner, or designee may order a biopsy of the vascularized organ or, if he or she is present during the physician's scheduled removal, may deny removal. If denial of removal is a possibility, the organ procurement organization may consult with a forensic pathologist, if available, as to the pathologist's opinion concerning the necessity of the organ in determining the cause of death. If a biopsy is ordered or removal is denied, the coroner, medical examiner, or designee must specify any reason in writing as part of the death report. Parts or all of the decedent's body that are anatomical gifts, other than vascularized organs, may be removed by a physician or technician ~~as authorized by the coroner, medical examiner, or designee with jurisdiction over the decedent.~~ A physician or technician who removes an organ from a decedent must complete a form, as specified by the Department of Health and Family Services (DHFS) by rule, and transmit the completed form to the coroner or medical examiner. The secretary of health and family services must appoint an advisory committee to assist DHFS in prescribing, by rule, ~~this form.~~ A physician or technician who removes cardiovascular tissue from a decedent must, upon request by a coroner or medical examiner, file a report with the coroner or medical examiner. ~~The agency recovering the part must maintain a permanent record of the name of the decedent, the name of any person who made an anatomical gift on behalf of the decedent, the date and purpose of the document of gift, the part removed, and the name of the person to whom the part was released. The agency must, upon request, make this record available to the coroner or medical examiner.~~

The substitute amendment also requires, for a decedent who is within the custody of a coroner or medical examiner and whose death occurred in a hospital, that any release of the decedent ~~as a potential tissue donor~~ be to the tissue bank with which the hospital has an agreement, as required under federal law. However, if that tissue bank is unwilling to receive the release, the tissue bank must notify the coroner or medical examiner, who then may notify concerning the availability any other tissue bank with which the coroner or medical examiner has an agreement.

for potential use in donating tissue

of the decedent

vascularized

As authorized by the coroner, medical examiner, or designee with jurisdiction over the decedent,

any part that is tissue or bone may be removed by a

and a physician, technician, or tissue bank employee who removes tissue, other than cardiovascular tissue, from a decedent, must complete a form

his or her

referral of the potential donor

additional

also

and tissue may be removed by a tissue bank employee

referral

of the coroner, medical examiner, or designee

designated by the coroner or medical examiner

forms must be transmitted

these forms

or tissue bank employee

of the tissue

and if the
gift is
madecoroner or medical examiner may remove the decedent's
body from the hospital in which the body is located

tissue

A tissue bank that is so notified, if it is willing to receive the release, must notify an available member of the decedent's family or the decedent's health care agent, under the order of priority, to request that the member or agent make an anatomical gift of all or part of the decedent's body. In such a case, the hospital in which the decedent's death occurred must either enter into a written agreement with this tissue bank authorizing the tissue bank to remove the tissue in the hospital or release the decedent to the tissue bank for removal of the tissue in another place.

If a decedent is within the custody of a coroner or medical examiner, the death occurred *outside* a hospital, and the coroner or medical examiner refers the decedent as a potential tissue donor, the substitute amendment requires that any such referral be made to one or more tissue banks with which the coroner or medical examiner has a written agreement. The agreement may be made only after the coroner or medical examiner has considered a number of factors concerning the tissue bank, and the agreement is subject to review and approval by the corporation counsel of the applicable county and ~~under a passive review process~~ by the applicable county board. Any tissue bank to which referral is made must be accredited by the American Association of Tissue Banks or audited at least once every two years by an organization that is accredited by the American Association of Tissue Banks.

or the
decedent's
body
was
removed from
a
hospital

general referral

Standard

INSERT A

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

1 SECTION 1. 157.06 (title) of the statutes is repealed and recreated to read:

2 157.06 (title) **Anatomical gifts.**

3 SECTION 2. 157.06 (2) (j) of the statutes is amended to read:

4 157.06 (2) (j) In the absence of contrary indications by the donor, an anatomical
5 gift of a part of a human body is neither a refusal to give other parts of the body nor
6 a limitation on an anatomical gift under sub. (3) or on a removal or release of other
7 parts of the body under sub. (4) ~~or (4m)~~. ¹ gov (4r)

8 SECTION 3. 157.06 (4) (title) of the statutes is amended to read:

9 157.06 (4) (title) NOTIFICATION AND AUTHORIZATION AUTHORIZATION BY CORONER ^(CS)

10 OR MEDICAL EXAMINER; ~~DECEDENT NOT A DONOR~~

NO EVIDENCE OF ANATOMICAL
GIFT

11 SECTION 4. 157.06 (4) (am) (intro.) of the statutes is amended to read:

1 157.06 (4) (am) (intro.) The coroner or medical examiner may release and
 2 permit the removal of a part from, a decedent specified in par. (ag) within that
 3 official's custody, for transplantation or therapy, if all of the following apply:

4 **SECTION 5.** 157.06 (4) (b) of the statutes is amended to read:

5 157.06 (4) (b) ~~An official releasing, and permitting~~ A coroner or medical
 6 examiner who releases, and permits the removal of a part of, a human body under
 7 this subsection shall maintain a permanent record of the name of the decedent, the
 8 name of the person making the request, the date and purpose of the request, the part
 9 of the body requested, and the name of the person to whom it was released.

10 **SECTION 6.** 157.06 (4m) of the statutes is created to read:

11 157.06 (4m) AUTHORIZATION BY CORONER OR MEDICAL EXAMINER; ~~DECEDENT~~ POTENTIAL DONATIONS
 12 ~~DONOR~~ (a) Subject to par. (b), for a decedent who meets the criteria for a OF ORGANS AND
 13 determination of death under s. 146.71, who is a donor or of whom an anatomical gift TISSUE
 14 has been made under sub. (3), and who is within the jurisdiction of a coroner or
 15 medical examiner under ch. 979, any vascularized organ that is an anatomical gift
 16 may be removed by a physician, within a time period compatible with preservation
 17 of the organ for purposes of transplantation, if all of the following take place:

18 1. Immediately after ~~the administrator of~~ decedent or decedent the hospital in which the donor ~~or~~ of the
 19 potential donor is located, ~~or a representative designated by the administrator,~~
 20 contacts the organ procurement organization designated for the region of which the
 21 hospital is a part concerning the potential donation, the organ procurement
 22 organization shall, by oral conversation, provide notice of the intended removal to
 23 the coroner or medical examiner or his or her designee and shall provide notice to the of the
 24 district attorney or his or her designee. referral of the donor, potential
decedent or decedent

including to a
tissue bank under the requirement

Sub
(4r)

CS

POTENTIAL DONATIONS
OF ORGANS AND
TISSUE

decedent or decedent

of the

of the
referral

of the
referral of the donor, potential
decedent or decedent

designated by the coroner, medical examiner, or designee

1 2. The coroner or medical examiner or his or her designee has the opportunity
2 to be present during the physician's removal of the vascularized organ if, in the
3 judgment of the coroner, medical examiner, or designee, the organ may be necessary
4 in determining the cause of death.

he or she

5 (b) If, in the judgment of the coroner, medical examiner, or designee specified
6 in par. (a) the vascularized organ may be necessary in determining the cause of
7 death, the coroner, medical examiner, or designee may order a biopsy of the
8 vascularized organ or, if the coroner, medical examiner, or designee is present during
9 the physician's scheduled removal, may deny removal. If denial of removal is a
10 possibility, the organ procurement organization may consult with a forensic
11 pathologist, if available, as to the pathologist's opinion concerning the necessity of
12 the organ in determining the cause of death. If the biopsy is ordered or the removal
13 is denied, the coroner, medical examiner, or designee shall specify, in writing as part
14 of any death report required under ch. 979, any reasons for determining that the
15 organ may be involved in the cause of death.

of the vascularized organ

the

vascularized

and any part that is tissue or bone may be removed by a

16 (c) For a decedent specified under par. (a), any part other than a vascularized
17 organ that is an anatomical gift may be removed by a physician or technician, within
18 a time period compatible with preservation of the part for purposes of
19 transplantation, as authorized by the coroner, medical examiner, or designee with
20 jurisdiction over the decedent.

or tissue bank employee

under the requirements of this section

21 (cm) A physician or technician who removes an organ from a decedent under
22 this subsection shall complete a form, as specified in sub. (9m), and transmit the
23 completed form to the coroner or medical examiner with jurisdiction over the
24 decedent.

(d) A physician ^{or technician} who removes cardiovascular tissue from a decedent under this subsection shall, upon request of the coroner or medical examiner, file with the coroner or medical examiner ^{with jurisdiction over the} a report detailing the condition ^{decedent} of the cardiovascular tissue and its relationship to the cause of death. The report may include a biopsy or medically approved sample, if available, from the part.

(e) If a coroner or medical examiner or his or her designee releases and permits the removal of a part under this subsection, the recovering agency shall maintain a permanent record of the name of the decedent, the name of the person, if any, who made an anatomical gift under sub. (3), the date and purpose of the document of gift, the part of the body removed, and the name of the person to whom the part was released. The recovering agency shall make the record under this paragraph available, ^{upon request,} to the coroner or medical examiner.

INSERT 6-12

SECTION 7. 157.06 (4r) of the statutes is created to read:

157.06 (4r) AUTHORIZATION BY CORONER OR MEDICAL EXAMINER; ~~DONEE~~. (a) 1. If a decedent is within the custody of a coroner or medical examiner, and the death occurred in a hospital, any release ^{for} by the hospital of the decedent as a potential tissue donor shall be to the tissue bank with which the hospital has an agreement under 42 CFR 482.45 (a) (2). However, if such a tissue bank is unwilling to receive the ^{tissue donation} release, the tissue bank shall so notify the coroner or medical examiner.

2. Upon receipt of a notification under subd. 1., the coroner or medical examiner may notify any other tissue bank with which the coroner or medical examiner has an agreement under par. (b) of the availability of the decedent as a potential tissue donor.

3. Upon receipt of a notification under subd. 2., the tissue bank so notified, if willing to receive the ^{tissue donation} release, shall contact an available individual, under the priority

1 established in sub. (3) (a), to request that the individual make an anatomical gift of
2 all or a part of the decedent's ~~body~~ ^{tissue}.

3 4. If subds. 2. and 3. apply, the hospital in which the decedent's death occurred
4 shall do one of the following:

- 5 a. Enter into a written agreement with the tissue bank specified in subd. 3. that
6 authorizes the tissue bank to remove the decedent's tissue in the hospital.
7 b. Release the decedent to the tissue bank specified in subd. 3. for removal of
8 the decedent's tissue in a place other than in the hospital.

9 (b) ^{when} If a decedent is within the custody of a coroner or medical examiner, the
10 death occurred outside a hospital, and the coroner or medical examiner refers the
11 decedent as a potential tissue donor, any such referral shall be made under the
12 following conditions:

13 1. Subject to ^{subd. 2.} ~~subd. 2.~~ the coroner or medical examiner, after considering a
14 tissue bank's history, services, traditional referral patterns, geographic service area,
15 and tissue distribution record and any other criteria required for consideration by
16 the corporation counsel of the applicable county, enters into a written agreement
17 with one or more tissue banks to which the coroner or medical examiner shall refer
18 decedents ^{for} ~~as~~ potential tissue donors. ^{subds. 2., 3., and 4.} <sup>or the decedent was transferred to ✓
the coroner or medical examiner under par. (a) 4.</sup>

19 2. Any agreement under subd. 1. is subject to review and approval by the
20 following:

- 21 a. The corporation counsel of the applicable county.
22 b. The county board of the applicable county. ^{if} ~~if~~ within 60 days after any
23 approval by the corporation counsel and transmittal of the agreement to the county
24 board, the county board takes no action, the agreement is approved. ^{all of} ~~However, if~~

<sup>may approve or disapprove the agreement
if the county board</sup>

1 within that period the county board requests review, the agreement is approved only
2 if the county board approves it or takes no action on it.

3 3. A tissue bank under this paragraph is accredited by the American
4 Association of Tissue Banks or audited at least once every 2 years by an organization
5 that is accredited by the American Association of Tissue Banks.

INSERT 8-5

6 SECTION 8. 157.06 (5) (bm) of the statutes is amended to read:

7 157.06 (5) (bm) If at or near the time of death of a patient a hospital knows that
8 an anatomical gift of all or a part of the patient's body has been made under sub. (3)
9 (a), that a release and removal of a part of the patient's body has been permitted
10 under sub. (4) or (4m) or that a patient or an individual identified as in transit to the
11 hospital is a donor, the hospital shall notify the donee if one is named and known to
12 the hospital. If a donee is neither named nor known to the hospital, the hospital shall
13 notify an appropriate procurement organization. The hospital shall cooperate in the
14 implementation of the anatomical gift or release and removal of a part of the body
15 of the patient or individual.

CS
FORMS FOR REMOVAL
OF ORGANS AND
CERTAIN TISSUES

16 SECTION 9. 157.06 (9m) of the statutes is created to read:

17 157.06 (9m) ~~ORGAN REMOVAL FORM; RULES.~~ The department of health and family
18 services shall promulgate rules prescribing ^{all of the following:} ~~an organ removal form for use under sub.~~

19 ~~(4m) (cm)~~

20 SECTION 10. 157.06 (11) of the statutes is repealed.

21 SECTION 11. 157.06 (12) of the statutes is repealed.

22 SECTION 12. 979.01 (5) of the statutes is created to read:

23 979.01 (5) Under the circumstances specified in s. 157.06 (4r) (a), a coroner or
24 medical examiner may release custody of a decedent whose death occurred in a
25 hospital.

INSERT 8-19

for removal of organs and
a form for removal of tissue; other than
cardiovascular
tissue

SECTION 13. Nonstatutory provisions.

AND TISSUE

(1) ORGAN REMOVAL FORM; ADVISORY COMMITTEE; EMERGENCY RULES.

(a) The secretary of health and family services shall appoint an advisory committee under section 15.04 (1) (c) of the statutes that shall include coroners, medical examiners, organ procurement organization personnel, and district attorneys, to assist the department of health and family services in prescribing, by rule, an organ removal form for use under section 157.06 (4m) (e) of the statutes, as created by this act.

(b) After consulting with the advisory committee under paragraph (a), by the first day of the 4th month beginning after the effective date of this subsection, the department of health and family services shall, using the procedure under section 227.24 of the statutes, promulgate the rules required under section 157.06 (9m) of the statutes, as created by this act, for the period before the effective date of the permanent rules promulgated under section 157.06 (9m) of the statutes, as created by this act, but not to exceed the period authorized under section 227.24 (1) (c) and (2) of the statutes. Notwithstanding section 227.24 (1) (a), (2) (b), and (3) of the statutes, the department is not required to provide evidence that promulgating a rule under this paragraph as an emergency rule is necessary for the preservation of the public peace, health, safety, or welfare and is not required to provide a finding of emergency for a rule promulgated under this paragraph.

(END)

forensic pathologists

D-NOTE

**2005-2006 DRAFTING INSERT
FROM THE
LEGISLATIVE REFERENCE BUREAU**

LRBs0425/lins
DAK:lmk:ch

INSERT A

NOT Any agreement entered into after the date on which the bill becomes an act must conform to these requirements; and any existing agreement must conform to the requirements by October 1, 2007. ✓

INSERT 6-12

1 (e) 1. A physician who removes an organ from a decedent under this subsection
2 shall complete a form, as specified in sub. (9m) (a). ✓

3 2. A physician, technician, or tissue bank employee who removes tissue, other
4 than cardiovascular tissue, from a decedent under this subsection shall complete a
5 form, as specified in sub. (9m) (b). ✓

6 3. After completing a form under this paragraph, the physician, technician, or
7 tissue bank employee shall transmit the form to the coroner or medical examiner
8 with jurisdiction over the decedent. ✓

INSERT 7-8

9 4. If the coroner or medical examiner communicates to the hospital that subds.
10 2. and 3. ✓ apply and if consent is given for an anatomical gift, the hospital shall
11 transfer the decedent to the coroner or medical examiner. ✓

INSERT 8-5

12 4. All of the following applies to an agreement by a coroner or medical examiner
13 with one or more tissue banks to which the coroner or medical examiner refers
14 decedents for potential donation of tissue: ✓

15 a. Any such agreement that is entered into after the effective date of this
16 subdivision unit [revisor inserts date], shall conform to the requirements of subd. ^S
17 1. to 3. ✓

18 b. Any such agreement that exists on the effective date of this subdivision unit
19 [revisor inserts date], shall conform to the requirements of subd. ^S 1. to 3. by October

1 1, 2007, unless the agreement expires before that date and is not renegotiated or
2 renewed. ✓

INSERT 8-19 ✓

3 (a) A form for removal of organs for use under sub. (4m) (e) 1. and 3.

4 (b) A form for removal of tissue, other than cardiovascular tissue, for use under
5 sub. (4m) (e) 2. and 3. ✓

6

**DRAFTER'S NOTE
FROM THE
LEGISLATIVE REFERENCE BUREAU**

LRBs0425/P2dn
DAK:lmk:ch

(date)

To Representative Wieckert:

1. Please note my changes to s. 157.06 (4) (title) and (4) (am) (intro.), stats. I made these changes to distinguish s. 157.06 (4), stats. (in which there is no evidence that the decedent has made or refused to make an anatomical gift) from s. 157.06 (4m), as created, which concerns a donor or individual for whom an anatomical gift has been made. I also wanted to indicate that, for s. 157.06 (4) (am), stats., the requirements created in s. 157.06 (4r) apply. Please review. ✓

2. Please note that, in restructuring s. 157.06 (4m) (e), as requested, certain requirements of tissue banks were, under the instructions, eliminated. Please review. ✓

Debora A. Kennedy
Managing Attorney
Phone: (608) 266-0137
E-mail: debora.kennedy@legis.state.wi.us

DRAFTER'S NOTE
FROM THE
LEGISLATIVE REFERENCE BUREAU

LRBs0425/1dn
DAK:lmk:rs

January 9, 2006

To Representative Wieckert:

1. Please note my changes to s. 157.06 (4) (title) and (4) (am) (intro.), stats. I made these changes to distinguish s. 157.06 (4), stats., (in which there is no evidence that the decedent has made or refused to make an anatomical gift) from s. 157.06 (4m), as created, which concerns a donor or individual for whom an anatomical gift has been made. I also wanted to indicate that, for s. 157.06 (4) (am), stats., the requirements created in s. 157.06 (4r) apply. Please review.
2. Please note that, in restructuring s. 157.06 (4m) (e), as requested, certain requirements of tissue banks were, under the instructions, eliminated. Please review.

Debora A. Kennedy
Managing Attorney
Phone: (608) 266-0137
E-mail: debora.kennedy@legis.state.wi.us

6-3070

Kennedy, Debora

From: Becher, Scott
Sent: Tuesday, January 10, 2006 5:27 PM
To: Kennedy, Debora
Subject: FW: Telephone conversation with Jeff Jentzen

Debora-

What would be the ramification of this?

Scott Becher
Rep. Wieckert

From: Dalessandro Anthony M [mailto:am.dalessandro@hosp.wisc.edu]
Sent: Tuesday, January 10, 2006 5:11 PM
To: Becher, Scott
Cc: Maroney Lisa A.; pcc@quarles.com
Subject: Telephone conversation with Jeff Jentzen

Scott, As per our phone conversation with Jeff Jentzen we discussed the following: 1.) Changing the word "may" on line 10, page 5 of the substitute amendment to "shall" and striking the words "if available" on line 12, page 5. We also discussed striking the word "physician's" on line 9, page 5 and have it read "is present during the scheduled removal", I wanted to be sure after checking with Deborah that this does not change the intent of the legislation of the requirement to be present. I don't think it does but I sure do not want to play the role of a drafting attorney. After our conversation I noted that on line 2, page 5 that "physician" was also there in regards to removal and if one "physician" is stricken should the other "physician" also be stricken so long as our intent of requiring the coroner, medical examiner or their designee to be present during the removal to deny is not altered. Thanks. Tony

Anthony M.D'Alessandro M.D.
Professor of Surgery
Executive Director UWHC Organ Procurement Organization
Tel: 608-263-2318
Cell: 608-239-1055
Fax: 608-262-9099

Kennedy, Debora

From: Sweet, Richard
Sent: Wednesday, January 11, 2006 11:34 AM
To: Kennedy, Debora
Cc: Becher, Scott
Subject: AB 830 sub

Debora,

Scott Becher asked me to e-mail you a change to the sub to AB 830 (LRBs0425/1)--

Page 7, line 4: delete "if consent is" and substitute "that consent has been".

Thanks.

Dick Sweet

Richard Sweet
Senior Staff Attorney
Wisconsin Legislative Council
(608)266-2982
richard.sweet@legis.state.wi.us

TELEPHONE DRAFTING INSTRUCTIONS

Drafting instructions received by Debora Kennedy.

DATE:

1/11/06

CONVERSATION
WITH:

Michelle Mittenner

OF:

TELEPHONE NO:

692-8541

REGARDING LRB #
OR DRAFT TOPIC:

50425/1

INSTRUCTIONS:

Concerned re eff date requirements for agreements w tissue banks and that, under 157.06(4r)(b) 4. b., renegotiation or renewal cd. be made outside of regnts.

DAK: renegot or renewal must be made under (4r)(b) 4-a. + can draft to express that

(p. 8, I. 13 : add: "under subd. unit 4-a.")

11/06 Mtg. : Scott Becher, Dr. Alessandro, 30425/1
Lisa Maroney,
Jeff Jentzen

Jeff Jentzen wants to change request that we
be present during removal in order to
deny removal

Agrees to viewing organ in operating room

11/06 Telephone conversation : Scott Becher,
Alice O'Connor

Revised approved changes; she is
troubled by deleting "if available" re the
forensic pathologist

1/12/06 Telephone conversation

John Stanley, Dick Sweet, Scott Becker

① Explanation of changes by Jeff Gentgen, Laura Leitch, + Michelle Mattern

② p. 5, l. 10 - change "shall" (changed by Jeff Gentgen from "may" to "shall make a good faith effort to")



FRIDAY 1/13
State of Wisconsin
2005 - 2006 LEGISLATURE

LRBs0425/12

DAK:lmk:rs

↑
stays

ASSEMBLY SUBSTITUTE AMENDMENT,
TO 2005 ASSEMBLY BILL 830

Reagan ✓

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4 of the statutes; **relating to:** anatomical gifts and the powers and duties of
5 coroners and medical examiners, granting rule-making authority, and
6 providing an exemption from emergency rule procedures.

Analysis by the Legislative Reference Bureau

Currently, an individual who is at least 18 years of age may make an anatomical gift (donation of all or part of his or her body to take effect at the time or after he or she irreversibly ceases circulatory and respiratory functions or all functions of the brain). Also, certain members of a decedent's family or his or her health care agent under a power of attorney for health care may, under an order of priority, make an anatomical gift of all or a part of the decedent's body. If a decedent is within the custody of a coroner or medical examiner and there is no evidence that the decedent made or refused to make an anatomical gift, under certain circumstances the coroner or medical examiner may release and permit the removal of a part from the decedent's body for use in transplantation or therapy.

This substitute amendment creates additional requirements related to removal of a body part from a decedent who is within the jurisdiction of a coroner or medical

Schedule 2

examiner. If the decedent has made an anatomical gift or his or her family or health care agent has made an anatomical gift of all or part of the decedent's body, a physician may remove a vascularized organ (a heart, lung, liver, pancreas, kidney, intestine, or other organ that requires the continuous circulation of blood to remain useful for purposes of transplantation) within a time period in which the organ may be preserved for purposes of transplantation if (1) immediately after the hospital in which the donor, potential decedent, or decedent is located contacts the organ procurement organization concerning the potential donation, the organ procurement organization provides notice, by oral conversation, of the referral of the potential donor to the coroner or medical examiner or his or her designee and provides notice of the referral to the district attorney or his or her designee; and (2) the coroner or medical examiner or his or her designee has the opportunity to be present during the vascularized organ's removal if in the judgment of the coroner, medical examiner, or designee the organ may be necessary in determining the cause of death. However, also if, in the judgment of the coroner, medical examiner, or designee, the organ may be necessary in determining the cause of death, the coroner, medical examiner, or designee may order a biopsy of the vascularized organ or, if he or she is present during the ~~physician's~~ scheduled removal, may deny removal. If denial of removal is a possibility, the organ procurement organization ~~may~~ consult with a forensic pathologist designated by the coroner or medical examiner, ~~if~~ ^{available}, as to the pathologist's opinion concerning the necessity of the vascularized organ in determining the cause of death. If a biopsy is ordered or removal is denied, the coroner, medical examiner, or designee must specify any reason in writing as part of the death report. As authorized by the coroner, medical examiner, or designee with jurisdiction over the decedent, parts or all of the decedent's body that are anatomical gifts, other than vascularized organs, may be removed by a physician, any part that is tissue or bone may be removed by a technician, and tissue may be removed by a tissue bank employee. A physician who removes an organ from a decedent must complete a form, and a physician, technician, or tissue bank employee who removes tissue, other than cardiovascular tissue, from a decedent, must complete a form. The completed forms must be transmitted to the coroner or medical examiner. The secretary of health and family services must appoint an advisory committee to assist DHFS in prescribing, by rule, these forms. A physician, technician, or tissue bank employee who removes cardiovascular tissue from a decedent must, upon request by a coroner or medical examiner, file a report with the coroner or medical examiner.

The substitute amendment also requires, for a decedent who is within the custody of a coroner or medical examiner and whose death occurred in a hospital, that any release of the decedent for potential use in donating tissue be to the tissue bank with which the hospital has an agreement, as required under federal law. However, if that tissue bank is unwilling to receive the release, the tissue bank must notify the coroner or medical examiner, who then may notify concerning the availability of the tissue any other tissue bank with which the coroner or medical examiner has an agreement. A tissue bank that is so notified, if it is willing to receive the release, must notify an available member of the decedent's family or the decedent's health care agent, under the order of priority, to request that the member

shall make a good-faith effort to

has been ^{If the coroner or medical examiner informs the hospital that these circumstances exist and that} or agent make an anatomical gift of all or part of the decedent's tissue. ^{who} ~~In such a case~~ and if the gift is made, the coroner or medical examiner may remove the decedent's body from the hospital in which the body is located. ^{hospital must transfer the decedent to the}

If a decedent is within the custody of a coroner or medical examiner, the death occurred *outside* a hospital or the decedent's body was removed from a hospital, and the coroner or medical examiner refers the decedent as a potential tissue donor, the substitute amendment requires that any such referral be made to one or more tissue banks with which the coroner or medical examiner has a written general referral agreement. The agreement may be made only after the coroner or medical examiner has considered a number of factors concerning the tissue bank, and the agreement is subject to review and approval by the corporation counsel of the applicable county and by the applicable county board, and any tissue bank to which referral is made must be accredited by the American Association of Tissue Banks or audited at least once every two years by an organization that is accredited by the American Association of Tissue Banks. Any agreement entered into after the date on which the bill becomes an act must conform to these requirements; and any existing agreement must conform to the requirements by October 1, 2007.

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

1 **SECTION 1.** 157.06 (title) of the statutes is repealed and recreated to read:

2 **157.06** (title) **Anatomical gifts.**

3 **SECTION 2.** 157.06 (2) (j) of the statutes is amended to read:

4 157.06 (2) (j) In the absence of contrary indications by the donor, an anatomical
5 gift of a part of a human body is neither a refusal to give other parts of the body nor
6 a limitation on an anatomical gift under sub. (3) or on a removal or release of other
7 parts of the body under sub. (4), (4m), or (4r).

8 **SECTION 3.** 157.06 (4) (title) of the statutes is amended to read:

9 157.06 (4) (title) ~~NOTIFICATION AND AUTHORIZATION~~ AUTHORIZATION BY CORONER
10 OR MEDICAL EXAMINER; NO EVIDENCE OF ANATOMICAL GIFT.

11 **SECTION 4.** 157.06 (4) (am) (intro.) of the statutes is amended to read:

12 157.06 (4) (am) (intro.) The coroner or medical examiner may release and
13 permit the removal of a part from, a decedent specified in par. (ag) within that

1 official's custody, for transplantation or therapy, including to a tissue bank under the
2 requirements of sub. (4r), if all of the following apply:

3 **SECTION 5.** 157.06 (4) (b) of the statutes is amended to read:

4 157.06 (4) (b) ~~An official releasing, and permitting~~ A coroner or medical
5 examiner who releases, and permits the removal of a part of, a human body under
6 this subsection shall maintain a permanent record of the name of the decedent, the
7 name of the person making the request, the date and purpose of the request, the part
8 of the body requested, and the name of the person to whom it was released.

9 **SECTION 6.** 157.06 (4m) of the statutes is created to read:

10 157.06 (4m) AUTHORIZATION BY CORONER OR MEDICAL EXAMINER; POTENTIAL
11 DONATIONS OF ORGANS AND TISSUE. (a) Subject to par. (b), for a decedent who meets the
12 criteria for a determination of death under s. 146.71, who is a donor or of whom an
13 anatomical gift has been made under sub. (3), and who is within the jurisdiction of
14 a coroner or medical examiner under ch. 979, any vascularized organ that is an
15 anatomical gift may be removed by a physician, within a time period compatible with
16 preservation of the organ for purposes of transplantation, if all of the following take
17 place:

18 1. Immediately after the hospital in which the donor, potential decedent, or
19 decedent is located contacts the organ procurement organization designated for the
20 region of which the hospital is a part concerning the potential donation, the organ
21 procurement organization shall, by oral conversation, provide notice to the coroner
22 or medical examiner or his or her designee of the referral of the donor, potential
23 decedent, or decedent and shall provide notice of the referral to the district attorney
24 or his or her designee.

shall make a
good-faith effort to

scheduled

2. The coroner or medical examiner or his or her designee has the opportunity to be present during the ~~physician's~~ removal of the vascularized organ if, in the judgment of the coroner, medical examiner, or designee, the organ may be necessary in determining the cause of death.

(b) If, in the judgment of the coroner, medical examiner, or designee specified in par. (a) the vascularized organ may be necessary in determining the cause of death, the coroner, medical examiner, or designee may order a biopsy of the vascularized organ or, if the coroner, medical examiner, or designee is present during the ~~physician's~~ scheduled removal, he or she may deny removal of the vascularized organ. If denial of removal is a possibility, the organ procurement organization ~~may~~ consult with ^a ~~the~~ forensic pathologist designated by the coroner, medical examiner, or designee ^a ~~if available~~, as to the pathologist's opinion concerning the necessity of the vascularized organ in determining the cause of death. If the biopsy is ordered or the removal is denied, the coroner, medical examiner, or designee shall specify, in writing as part of any death report required under ch. 979, any reasons for determining that the vascularized organ may be involved in the cause of death.

(c) For a decedent specified under par. (a), as authorized under the requirements of this section by the coroner, medical examiner, or designee with jurisdiction over the decedent, any part other than a vascularized organ that is an anatomical gift may be removed by a physician and any part that is tissue or bone may be removed by a technician or tissue bank employee, within a time period compatible with preservation of the part for purposes of transplantation.

(d) A physician, technician, or tissue bank employee who removes cardiovascular tissue from a decedent under this subsection shall, upon request of the coroner or medical examiner, file with the coroner or medical examiner with

1 jurisdiction over the decedent a report detailing the condition of the cardiovascular
2 tissue and its relationship to the cause of death. The report may include a biopsy or
3 medically approved sample, if available, from the part.

4 (e) 1. A physician who removes an organ from a decedent under this subsection
5 shall complete a form, as specified in sub. (9m) (a).

6 2. A physician, technician, or tissue bank employee who removes tissue, other
7 than cardiovascular tissue, from a decedent under this subsection shall complete a
8 form, as specified in sub. (9m) (b).

9 3. After completing a form under this paragraph, the physician, technician, or
10 tissue bank employee shall transmit the form to the coroner or medical examiner
11 with jurisdiction over the decedent.

12 **SECTION 7.** 157.06 (4r) of the statutes is created to read:

13 157.06 (4r) AUTHORIZATION BY CORONER OR MEDICAL EXAMINER; TISSUE BANKS. (a)

14 1. If a decedent is within the custody of a coroner or medical examiner, and the death
15 occurred in a hospital, any release of the decedent for potential donation of tissue
16 shall be to the tissue bank with which the hospital has an agreement under 42 CFR
17 482.45 (a) (2). However, if such a tissue bank is unwilling to receive the tissue
18 donation, the tissue bank shall so notify the coroner or medical examiner.

19 2. Upon receipt of a notification under subd. 1., the coroner or medical examiner
20 may notify any other tissue bank with which the coroner or medical examiner has
21 an agreement under par. (b) of the availability of the decedent as a potential tissue
22 donor.

23 3. Upon receipt of a notification under subd. 2., the tissue bank so notified, if
24 willing to receive the tissue donation, shall contact an available individual, under the

1 priority established in sub. (3) (a), to request that the individual make an anatomical
2 gift of all or a part of the decedent's tissue.

3 4. If the coroner or medical examiner ~~communicates to~~ ^{has been} the hospital that subds.
4 2. and 3. apply and ~~if~~ ^{that} consent ~~is~~ given for an anatomical gift, the hospital shall
5 transfer the decedent to the coroner or medical examiner.

6 (b) When a decedent is within the custody of a coroner or medical examiner, the
7 death occurred outside a hospital or the decedent was transferred to the coroner or
8 medical examiner under par. (a) 4., and the coroner or medical examiner refers the
9 decedent as a potential tissue donor, any such referral shall be made under the
10 following conditions:

11 1. Subject to subds. 2., 3., and 4., the coroner or medical examiner, after
12 considering a tissue bank's history, services, traditional referral patterns,
13 geographic service area, and tissue distribution record and any other criteria
14 required for consideration by the corporation counsel of the applicable county, enters
15 into a written, general referral agreement with one or more tissue banks to which
16 the coroner or medical examiner shall refer decedents for potential donation of
17 tissue.

18 2. Any agreement under subd. 1. is subject to review and approval by all of the
19 the following:

- 20 a. The corporation counsel of the applicable county.
- 21 b. The county board of the applicable county. Within 60 days after any approval
22 by the corporation counsel and transmittal of the agreement to the county board, the
23 county board may approve or disapprove the agreement. If the county board takes
24 no action, the agreement is approved.

1 3. A tissue bank under this paragraph is accredited by the American
2 Association of Tissue Banks or audited at least once every 2 years by an organization
3 that is accredited by the American Association of Tissue Banks.

4 4. All of the following applies to an agreement by a coroner or medical examiner
5 with one or more tissue banks to which the coroner or medical examiner refers
6 decedents for potential donation of tissue:

7 a. Any such agreement that is entered into after the effective date of this
8 subdivision unit [revisor inserts date], shall conform to the requirements of subds.
9 1. to 3.

10 b. Any such agreement that exists on the effective date of this subdivision unit
11 [revisor inserts date], shall conform to the requirements of subds. 1. to 3. by
12 October 1, 2007, unless the agreement expires before that date and is not
13 renegotiated or renewed. *under subd. unit 4, a*

14 **SECTION 8.** 157.06 (5) (bm) of the statutes is amended to read:

15 157.06 (5) (bm) If at or near the time of death of a patient a hospital knows that
16 an anatomical gift of all or a part of the patient's body has been made under sub. (3)
17 (a), that a release and removal of a part of the patient's body has been permitted
18 under sub. (4) or (4m) or that a patient or an individual identified as in transit to the
19 hospital is a donor, the hospital shall notify the donee if one is named and known to
20 the hospital. If a donee is neither named nor known to the hospital, the hospital shall
21 notify an appropriate procurement organization. The hospital shall cooperate in the
22 implementation of the anatomical gift or release and removal of a part of the body
23 of the patient or individual.

24 **SECTION 9.** 157.06 (9m) of the statutes is created to read:

1 157.06 (9m) FORMS FOR REMOVAL OF ORGANS ND CERTAIN TISSUES; RULES. The
2 department of health and family services shall promulgate rules prescribing all of
3 the following:

4 (a) A form for removal of organs for use under sub. (4m) (e) 1. and 3.

5 (b) A form for removal of tissue, other than cardiovascular tissue, for use under
6 sub. (4m) (e) 2. and 3.

7 **SECTION 10.** 157.06 (11) of the statutes is repealed.

8 **SECTION 11.** 157.06 (12) of the statutes is repealed.

9 **SECTION 12. Nonstatutory provisions.**

10 (1) ORGAN AND TISSUE REMOVAL FORMS; ADVISORY COMMITTEE; EMERGENCY RULES.

11 (a) The secretary of health and family services shall appoint an advisory
12 committee under section 15.04 (1) (c) of the statutes that shall include coroners,
13 forensic pathologists, medical examiners, organ procurement organization
14 personnel, tissue banks, and district attorneys, to assist the department of health
15 and family services in prescribing, by rule, a form for removal of organs and a form
16 for removal of tissue, other than cardiovascular tissue, for use under section 157.06
17 (4m) (e) of the statutes, as created by this act.

18 (b) After consulting with the advisory committee under paragraph (a), by the
19 first day of the 4th month beginning after the effective date of this subsection, the
20 department of health and family services shall, using the procedure under section
21 227.24 of the statutes, promulgate the rules required under section 157.06 (9m) of
22 the statutes, as created by this act, for the period before the effective date of the
23 permanent rules promulgated under section 157.06 (9m) of the statutes, as created
24 by this act, but not to exceed the period authorized under section 227.24 (1) (c) and
25 (2) of the statutes. Notwithstanding section 227.24 (1) (a), (2) (b), and (3) of the

1 statutes, the department is not required to provide evidence that promulgating a rule
2 under this paragraph as an emergency rule is necessary for the preservation of the
3 public peace, health, safety, or welfare and is not required to provide a finding of
4 emergency for a rule promulgated under this paragraph.

5 (END)

Emery, Lynn

From: Emery, Lynn
Sent: Friday, January 13, 2006 10:10 AM
To: Becher, Scott
Subject: LRB 05s0425/2 (attached)

Attachments: 05s0425/2



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